UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Offic
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/719,946	12/15/00	JOMAA	H 12964.19

EXAMINER	
KWON, B	
ART UNIT	PAPER NUMBER
1614	9

DATE MAILED: 11/06/01

HM22/1106

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/719,946	JOMAA, HASSAN	
	Examin r	Art Unit	
	Brian-Yong S Kwon	1614	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Application

Claims 6-14 are pending. Claims 1-5 are cancelled; Claims 6-14 are are newly added.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 10-14 recites a method of treating "a previously diagnosed inappropriate reaction or over-reaction of an individual's immune system". The specification fails to provide adequate support for the recitation of the various disease states or "a previously diagnosed inappropriate reaction or over-reaction of an individual's immune system" in claim 10-14. Although the present specification (in page 1, lines 14-19) discloses few examples of autoimmune disorders, it would be unreasonable to expect the many diseases or conditions that is related to the inappropriate reaction to the individual's immune system would respond to the method of claims 10-14. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re*

Wands, 8 USPQ 1400 (CAFC 1988) at 1404 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman, 230 USPQ 546 (BdApls) at 547* the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that defines those characteristics defining "a previously diagnosed inappropriate reaction or over-reaction of an individual's immune system" (or "autoimmune disorders"). The breadth of current claims reciting "a previously diagnosed inappropriate reaction or over-reaction of an individual's immune system" (or "autoimmune disorders) is too broad such that one having ordinary skilled in the art would not be able to use the invention commensurate in scope with these claims. The instant claims 10-14 read on any conditions or diseases that is related to inappropriate reaction to the individual's immune system, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Thus, Applicant fails to provide information sufficient to practice the claimed invention, absent undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is vague and indefinite as being unclear by reciting "treating a previously diagnosed inappropriate reaction over reaction of an individual's immune system". Does applicant mean "treating of autoimmune disorders or allergies"? Applicant is requested to clarify.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lyons et al. (GB 2312165 A) in view of Michael et al. (US 6174529B1).

Claims read a medicament comprising an autoantigen or allergen in combination with bisphosphonic acid, wherein the bisphosphonic acid is selected from the groups consisting of AMP, AEP, pamidronic acid, alendronic acid, AIMP, ibandronic acid, risedronic acid, zoledronic acid, cimadronic acid, and tiludronic acid; and excipient; a method of treating a previously diagnosed inappropriate reaction or over-reaction of an individual's immune system with said medicament.

Lyons et al. (GB 2312165 A) teaches the use of bisphosphonic acids (e.g., ibandronate) for treating chronic immune system activation disorders by an immunomodulatory action (see claim 1, 3, 11; page 1, lines 5-7; see also page 3, lines 32-34 of the instant specification for your reference).

Michael et al. teaches or suggests the use of antigens (e.g., insulin, thyroid proteins, acetyl choline receptor protein, Type II collagen, myelin basic protein) or allergens (e.g., dust, mites, bee venom, food allergens, animal dander, insect venoms, etc...) as "therapeutic protein (see column 1, lines 18-45; column 2, line 59-67; and column 3, lines 33-50) for treating autoimmune diseases or allergies.

The teaching of Lyons et al. differs from the claimed invention in the combination use of bisphosphonic acids in combination with autoantigens or allergens for the treatment of autoimmune disease or allergy. To incorporate such teaching into the teaching of Lyons et al., would have been obvious in view of Michael et al. who teaches or suggests the use of protein

antigen (e.g., myelin basic protein, acetyl choline receptor or type II collagen, insulin, thyroid protein, etc...) or allergens (e.g., dust, mites, bee venom, food allergens, animal dander, insect venoms, etc...) for treating autoimmune diseases or allergies.

The above references in combination make clear that bisphophonic acids and protein antigens or allergens have been individually used for the treatment of autoimmune diseases. It is obvious to combine two compositions each of which is taught by prior art to be useful for same purpose; idea of combining them flows logically from their having been individually taught in prior art. The combination of active ingredient with the same character is merely the additive effect of each individual component. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 6-14 are properly rejected under 35 U.S.C. 103.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Monday through Friday from 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600